# *Recent Updates to the National Drug Code (NDC) Directory and Electronic Drug Registration and Listing System (eDRLS)*


***Leyla Rahjou-Esfandiary***
***Soo Jin Park***
***Paul Loebach***

***Food and Drug Administration***
***Center for Drug Evaluation and Research***
***Office of Compliance***
***Drug Registration and Listing System***

# Background

- Under section 510 of the Act, and Part 207, with some limited exceptions, firms that manufacture, prepare, propagate, compound, or process drugs in the US or that are offered for import into the United States must be registered with the FDA. *21 U.S.C. 360(b), (c), (d), and (i).*
- Every person who is required to register must, at the time of initial registration, list all drugs manufactured, prepared, propagated, compounded, or processed for commercial distribution. *21 U.S.C. 360(j)(1) and also 21 C.F.R. 207.20.*
- As of June 1, 2009, registration and listing information is submitted electronically through the FDA Gateway using the Structured product Labeling format.

# NDC Directory

- FDA publishes the listed NDC numbers and the information submitted as part of the listing information in the NDC Directory.
- The NDC Directory contains ONLY information submitted to FDA by labelers
  - paper forms (old version only)
  - electronic SPLs (Old and New versions)

# NDC Directory Updates

- New NDC Directory
  - What's included?
    - Rx and OTC Drugs
    - Approved
      - ANDAs, NDAs, and BLAs
    - Unapproved
      - Homeopathics, Medical Gases, Other
  - What's NOT included?
    - API
    - Drugs for further processing
    - Bulk ingredients
    - Animal drugs
    - Blood related products

# NDC Directory Updates

- New NDC Directory
  - New structure and data elements in download files
    - Marketing Category
    - Pharmacologic Class
    - DEA Schedule
    - Product Type Name
    - 12 files to 2 files
    - Tab delimited text file and Spreadsheet version
  - Publications
    - Bi-monthly updates: around 1st and 15th of each month

# NDC Directory Updates

- Old NDC Directory
  - A final edition of the DRLS based NDC Directory was published around June 1, 2011
  - NDCs found are still considered listed
    - Unless discontinued by email
  - Email delisting will continue though December 2011
  - Begin updating quarterly starting October 2011

# eDRLS

- Some listing instructions:
  - Kit listing
    - Include components of kit and their NDC
    - Component NDC cannot match Kit NDC
  - Multi-level packaging
    - Outermost package codes are published
  - New listing validations
    - DUNS Validation
    - Assign new NDC number with change in physical characteristics of drug products
    - Ensure that the original set ID is utilized in subsequent submissions of an SPL file

# NDC Directory

- Assignment of an NDC number does not in any way denote FDA approval of the product. Any representation that creates an impression of official approval because of possession of an NDC number is misleading and constitutes misbranding. (21 CFR 207.39)
- Neither inclusion in the NDC Directory nor assignment of an NDC number is a determination that a product is a drug as defined by the FD&C Act, nor does either denote that a product is covered or eligible for reimbursement by Medicare, Medicaid or other payers.

# Establishment Registration

- New database
  - Drug Establishments Current Registration Site (DECRS)
  - What's included?
    - All current registration in DRLS
    - Newly registered or renewed in 2010 and 2011

# Establishment Registration

- DUNS number and FEI number
  - Obtain DUNS number before submitting
  - Include FEI if known
- Use two letter State Abbreviations
- Publications
  - DECRS
  - List of NDC Labeler code assignments

# Establishment Registration

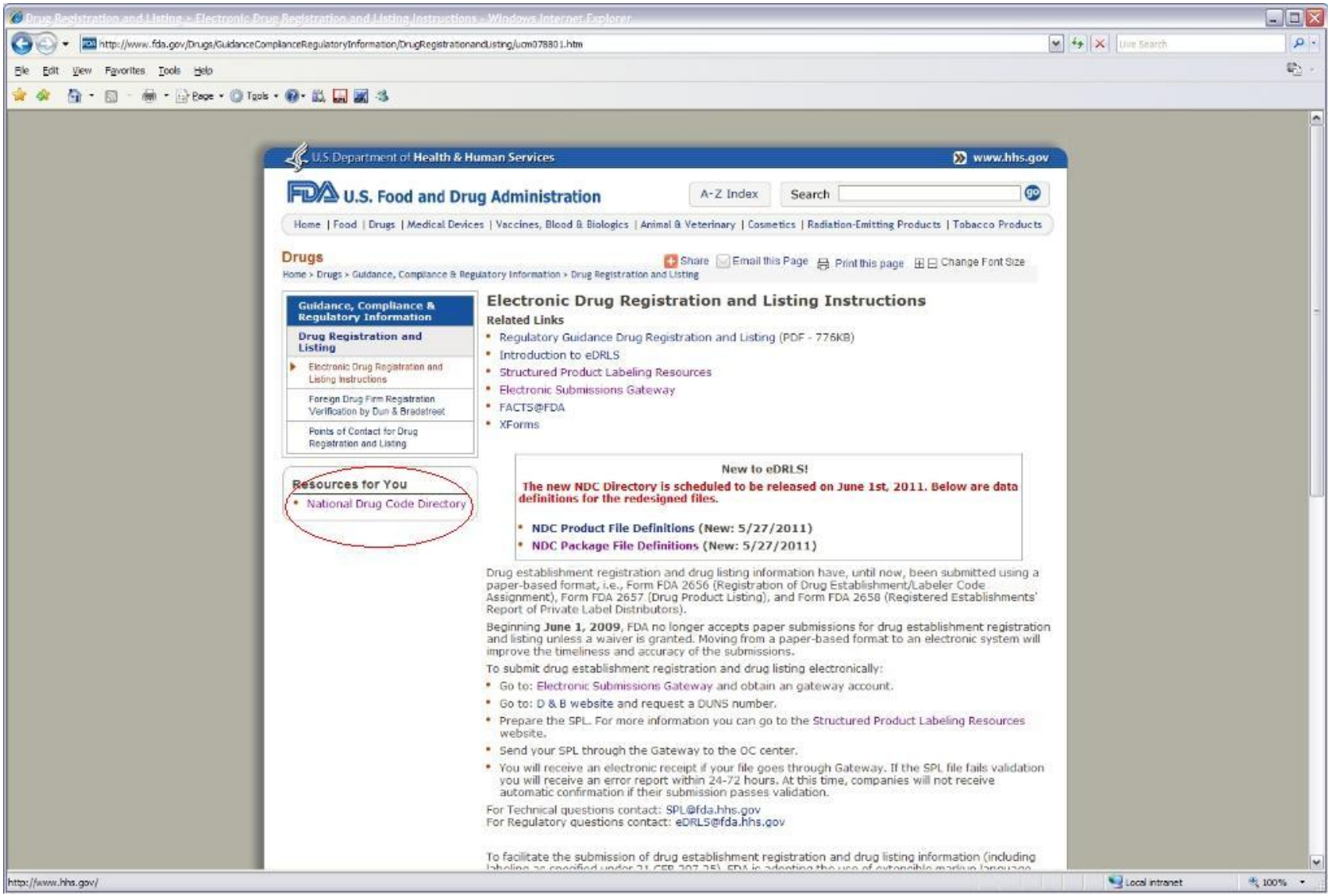
- Registration updates
  - No change notification
- Mergers/ buyouts
  - Name change via LC Request, Registration, and listing
- Update US Agent information in LC Request if firm is not required to register

# Proposed Rule

- Published August 2006
- Public comments
- FDA working groups
- Tentative finalized date 2012

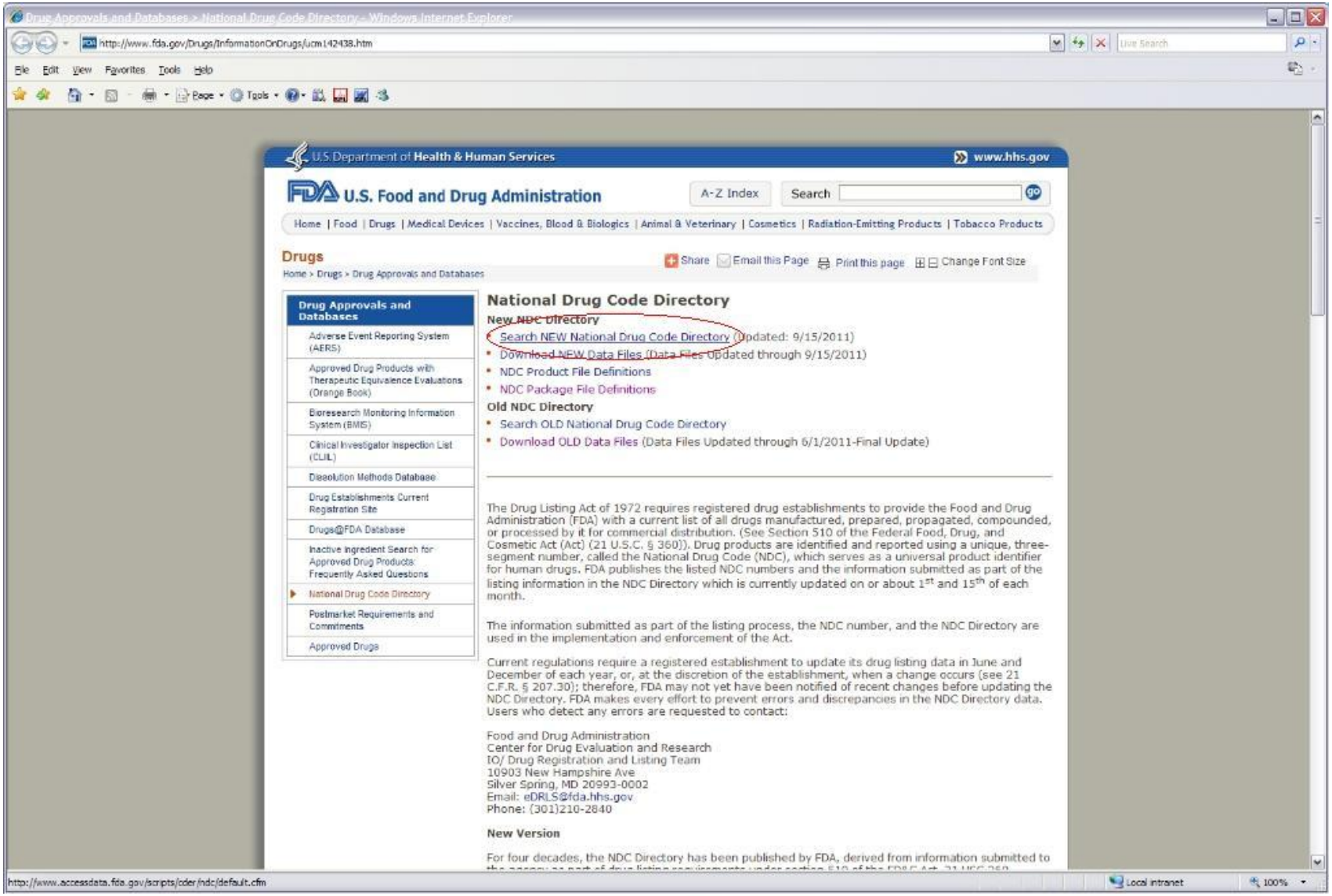
# NDC Directory – On Line

www.fda.gov/edrls



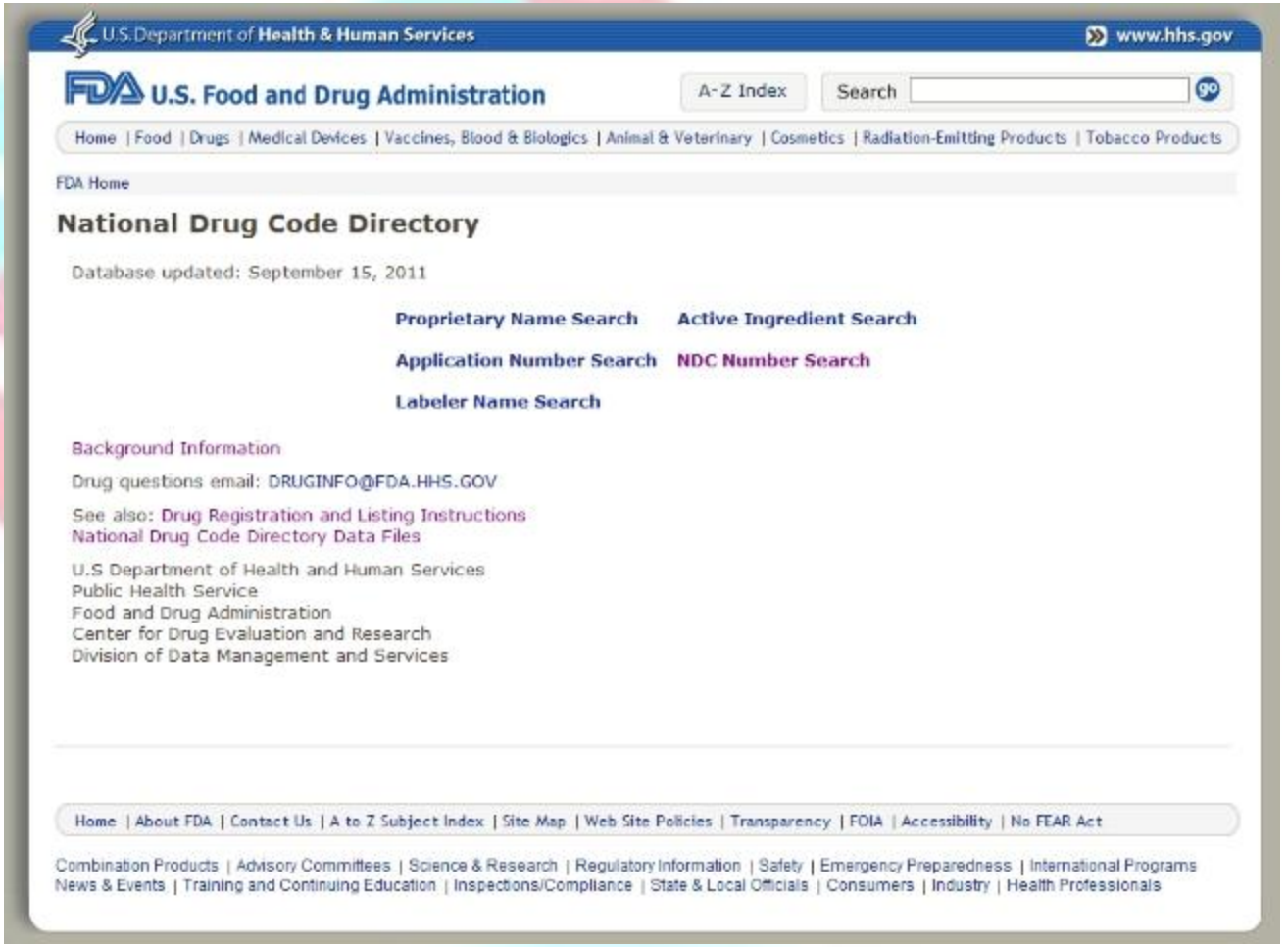
# NDC Directory On-Line

*Search on-line or download files*



# NDC Directory On-Line

## Search by NDC Number
*(Wildcard added to end of string)*



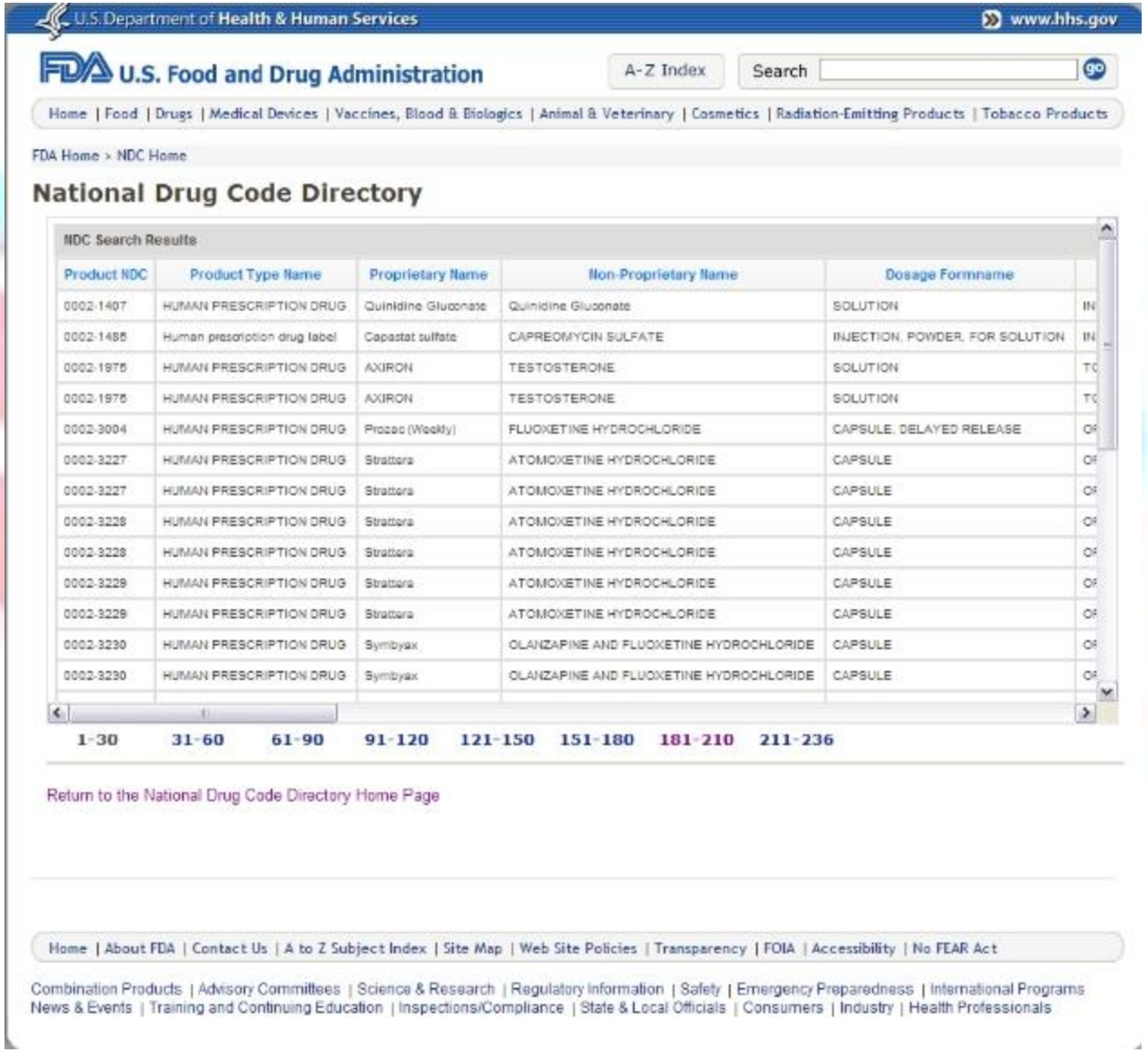
# NDC Directory On-Line

## Search by NDC Number
*(Wildcard added to end of string)*

# NDC Directory On-Line

## Search by NDC Number

*(Results)*



U.S. Department of Health & Human Services www.hhs.gov

U.S. Food and Drug Administration

A-Z Index | Search | go

Home | Food | Drugs | Medical Devices | Vaccines, Blood & Biologics | Animal & Veterinary | Cosmetics | Radiation-Emitting Products | Tobacco Products

FDA Home > NDC Home

**National Drug Code Directory**

NDC Search Results

| Product NDC | Product Type Name | Proprietary Name | Non-Proprietary Name | Dosage Formname | |
|---|---|---|---|---|---|
| 0002-1407 | HUMAN PRESCRIPTION DRUG | Quinidine Gluconate | Quinidine Gluconate | SOLUTION | IN |
| 0002-1485 | Human prescription drug label | Capastat sulfate | CAPREOMYCIN SULFATE | INJECTION, POWDER, FOR SOLUTION | IN |
| 0002-1975 | HUMAN PRESCRIPTION DRUG | AXIRON | TESTOSTERONE | SOLUTION | TO |
| 0002-1975 | HUMAN PRESCRIPTION DRUG | AXIRON | TESTOSTERONE | SOLUTION | TO |
| 0002-3004 | HUMAN PRESCRIPTION DRUG | Prozac (Weekly) | FLUOXETINE HYDROCHLORIDE | CAPSULE, DELAYED RELEASE | OR |
| 0002-3227 | HUMAN PRESCRIPTION DRUG | Strattera | ATOMOXETINE HYDROCHLORIDE | CAPSULE | OR |
| 0002-3227 | HUMAN PRESCRIPTION DRUG | Strattera | ATOMOXETINE HYDROCHLORIDE | CAPSULE | OR |
| 0002-3228 | HUMAN PRESCRIPTION DRUG | Strattera | ATOMOXETINE HYDROCHLORIDE | CAPSULE | OR |
| 0002-3228 | HUMAN PRESCRIPTION DRUG | Strattera | ATOMOXETINE HYDROCHLORIDE | CAPSULE | OR |
| 0002-3229 | HUMAN PRESCRIPTION DRUG | Strattera | ATOMOXETINE HYDROCHLORIDE | CAPSULE | OR |
| 0002-3229 | HUMAN PRESCRIPTION DRUG | Strattera | ATOMOXETINE HYDROCHLORIDE | CAPSULE | OR |
| 0002-3230 | HUMAN PRESCRIPTION DRUG | Symbyax | OLANZAPINE AND FLUOXETINE HYDROCHLORIDE | CAPSULE | OR |
| 0002-3230 | HUMAN PRESCRIPTION DRUG | Symbyax | OLANZAPINE AND FLUOXETINE HYDROCHLORIDE | CAPSULE | OR |

1-30 31-60 61-90 91-120 121-150 151-180 181-210 211-236

Return to the National Drug Code Directory Home Page

Home | About FDA | Contact Us | A to Z Subject Index | Site Map | Web Site Policies | Transparency | FOIA | Accessibility | No FEAR Act

Combination Products | Advisory Committees | Science & Research | Regulatory Information | Safety | Emergency Preparedness | International Programs
News & Events | Training and Continuing Education | Inspections/Compliance | State & Local Officials | Consumers | Industry | Health Professionals

# eSubmitter

- What is eSubmitter?
  - Software to create electronic submissions (SPL) to FDA
  - More user-friendly
  - Coming soon to Drug Registration and Listing
- Currently used by CDRH, CBER, CTP, CVM, for various types of submissions
- FDA eSubmitter FAQs: http://www.fda.gov/downloads/ForIndustry/FDAeSubmitter/UCM266914.pdf
- For technical assistance for eSubmitter software: esubmitter@fda.hhs.gov

# Questions?

Thank you!

eDRLS@fda.hhs.gov

www.fda.gov/edrls